

**Notice of Allowability**

Application No.

10/829,427

Examiner

Malgorzata A. Walicka

Applicant(s)

FURUKAWA ET AL.

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/08/06.
2. ☒ The allowed claim(s) is/are 11 and 12.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

Art Unit: 1652

Amendment and Request for Reconsideration filed August 8, 2006 is acknowledged. Claims 1-10 have been previously canceled. Claims 11-12 have been amended and are under examination.

## **DETAILED ACTION**

### **2. Objections**

#### **2.2. Claims**

Claim 11 was objected to in the Office action of May 9, 2006 (previous action), because the claim part (e) recited "after 10-minute heat". This objection is now withdrawn, because the claim has been amended.

### **3. Rejections**

#### **3.1. 35 U.S.C. 112, second paragraph**

Claim 11 was rejected under 35 U.S.C. 112, second paragraph, for recitation "optional temperature" and "up to at about 50° C". The rejection is now withdrawn, because the claim has been amended.

#### **3.2. 35 USC section 112, first paragraph**

##### **3.2.1. Written description**

Claim 12 was rejected in the previous action, for lack of description of structure of broadly claimed genus of sarcosine oxidases obtained from SEQ ID NO: 1 by deletion,

Art Unit: 1652

substitution, or addition of one or some amino acids retaining sarcosine oxidase activity.

This rejection is now withdrawn, because the claim has been amended.

### 3.2.2. Scope of enablement

Claims 11 and 12 were rejected in previous action as lacking enablement the full scope of enablement of the structure of the claimed invention. Rejection of claim 12 is withdrawn because claim 12 has been amended.

### 3.3. 35 U.S.C. 102

Claim 12 was rejected under 35 U.S.C. 102(b) as being anticipated by Nishiya Y. et al. (Analysis of Interaction between the Arthrobacter Sarcosine Oxidase and the Coenzyme Flavin Adenine Dinucleotide by Site-Directed Mutagenesis, Applied and Environmental Microbiology, 1996, 62(7), 2405-2410 and over Japanese published Patent application JP05115281-A, published May 14, 1993.

This rejection is now withdrawn, because claim 12 has been amended.

### 3.4. Provisional obviousness double patenting

Claim 12 was provisionally rejected as being unpatentable over claim 2 of copending Application No. 10/990,477. This rejection is now withdrawn because claim 2 of 10/990,477, as allowed, is not a conflicting claim to claim 12 of the instant application.

#### 4. Examiner's amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

(i) Please amend claim 11 to read:

11. A sarcosine oxidase, wherein said enzyme

(a) hydrolyzes 1 mol of sarcosine to produce 1 mol of glycine and 1 mol of formaldehyde;

(b) has an optimal pH of about 6.5;

(c) does not change its activity after being incubated at pH of between 6.0 and 11.0 for 5 hours at 25°C;

(d) has an optimal temperature of 60°C;

(e) is stable after heating for 10 minutes in 50 mM potassium phosphate buffer and at pH 7.5, at about 50°C;

(f) retains 90% of activity after 5 hours at pH 6.0 and 25°C and it retains 70% activity after 17 hours at pH 6.0 and 25°C;

(g) has a molecular weight of approximately 43,000 (SDS-PAGE); and

(h) has Km value of 5.9 mM at pH 6.5; and

Art Unit: 1652

wherein the sarcosine oxidase is encoded by a DNA derived by modifying a DNA having the nucleotide sequence represented by SEQ ID NO: 2, and has lysine at position 61, glycine at position 241, and histidine at position 324.

(ii) Please amend claim 12 to read:

12. A sarcosine oxidase comprising the amino acid sequence represented by SEQ ID NO: 1.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative James J. Kelly on October 31, 2006.

## **5. Allowance**

Claims 11 and 12 are allowed. Applicants have disclosed the sarcosine oxidase of SEQ ID NO:1. The enzyme is novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is


Art Unit: 1652

(571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.  
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Patent Examiner

  
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